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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/550,486	09/26/2005	Michio Kubota	KUBOTA 16	2976		
1444	7590	02/27/2009	EXAMINER			
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				WATTS, JENNA A		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/550,486	KUBOTA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JENNA A. WATTS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>20070301</u> .	6) <input type="checkbox"/> Other: ____ .

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It would be expected that the non-saccharide ingredient would have to be either hydrophobic or hydrophilic, therefore Claim 2 fails to properly limit independent Claim 1.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 4, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 3 and 4 appear to be a Markush claim, however, it is unclear whether “marine products and agricultural products” is a singular group within the Markush group or if they are separate groups within the Markush group. Appropriate correction is required.

5. Regarding Claim 7, it is unclear whether the term “amorphous” is referring to the overall final composition or to the properties of the saccharide-derivative on a molecular

level. The term amorphous is only used in Applicant's specification with reference to the powdery product produced (see instant specification, page 24, line 14, for example).

6. Regarding Claim 8, the phrase "allowing" is passive and it is unclear as to what positive active method steps are actually being performed according to the claim limitations.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandai et al. (U.S. Patent No. 5,780,620) in view of Oobae et al. (U.S.P.A. 2002/0042393).

11. Regarding Claim 1, Mandai teaches a method of using a saccharide derivative of alpha, alpha trehalose (Column 1, lines 11-13 and Column 2, lines 1-3) in various applications including as an additive in compositions comprising non-saccharide ingredients such as miso or soy powder or fruits and vegetables (Column 5, line 65 and Column 6, lines 38-39). Mandai teaches that the invention establishes a novel non-reducing oligosaccharide where one or several glucosyl groups are bound to both glucosyl groups in trehalose (Column 2, lines 1-3). Such a non-reducing oligosaccharide is deemed a saccharide derivative of alpha, alpha trehalose because Mandai teaches that trehalose has glucoses bound to each other via the alpha-1 and alpha 1 linkages (Column 1, lines 11-13), and Applicant has indicated that a saccharide derivative of alpha, alpha trehalose means a saccharide having a structure of binding any one selected from the group consisting of one or several glucosyl groups or residues to at least one glucose residue of alpha, alpha trehalose molecule (see instant Specification, Page 9, lines 27-29 and Page 10, lines 1-2). Thus, the oligosaccharide taught by Mandai is deemed a saccharide derivative of alpha, alpha trehalose.

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12. Mandai teaches that the properties of the oligosaccharide/saccharide derivative of alpha, alpha trehalose are favorably utilizable in the production of food products including foods, beverages, feeds and pet foods, as well as pharmaceutical compositions (Column 5, lines 30-34) and can be a stabilizer for activities or active ingredients in biologically-active substances (Column 6, lines 66-67). Mandai further teaches that the saccharide derivative of alpha, alpha trehalose can be mixed with other fillers, vehicles and/or binders and successively shaped into granule, globe, tablet, etc. (Column 5, lines 46-50).

13. However, Mandai does not specifically teach a method of powderizing a non-saccharide ingredient comprising mixing a non-saccharide ingredient with a saccharide derivative of alpha, alpha trehalose and powderizing the resulting mixture.

14. Oobae teaches a method of using a saccharide derivative of alpha, alpha trehalose (Page 3, Paragraphs 35 and 36) as an excipient in powders and the like which are used as medicine, food, etc. and a pharmaceutical composition containing the excipient (Page 1, Paragraph 1). Oobae teaches using a saccharide derivative of alpha, alpha trehalose because Oobae teaches that the trehalose used in the invention is preferably one that is prepared by treating starch degradation products with a glucose polymerization degree of 3 or higher with an enzyme capable of producing non-reducing sugars having a trehalose structure at its end (Page 4, Paragraph 36), and applicant refers to such a structure in the instant application on Page 9, lines 25-27.

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15. Ooebae teaches that the trehalose excipient is preferably used in a pharmaceutical composition prepared in a solid form, such as a powder (Page 5, Paragraph 45). Oobae teaches that the trehalose excipient used in the invention is especially useful for processing and formulating powder into a pharmaceutical composition (Page 5, Paragraph 44) and further teaches that the trehalose excipient imparts various physical properties required for preparing a pharmaceutical composition, including granulating properties, solubility, and miscibility (Page 12, Paragraph 154). Oobae teaches adding other additives such as binders, lubricants, flavoring materials, coloring, etc. to the pharmaceutical composition (Page 5, Paragraph 49 and Page 6, Paragraph 52). In particular, Ooebae teaches the addition of emulsifiers to the composition, such as xanthan gum (Page 6, Paragraph 55), which are deemed non-saccharide ingredients.

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the saccharide derivative of alpha, alpha trehalose, as taught by Mandai, to have been mixed with a non-saccharide ingredient and then further powdered, because Ooebae teaches that the saccharide derivative of alpha, alpha trehalose, is useful in preparing powders which are used as medicine, food, and in a pharmaceutical composition and such a saccharide derivative imparts desirable physical properties useful in preparing a pharmaceutical composition. One of ordinary skill would have been motivated to use the named saccharide derivative in a powder composition in order to create a product with desirable physical characteristics that is suitable for consumer use.

17. Regarding Claims 2 and 3, Oobae teaches that the non-saccharide ingredient is xanthan gum (Page 6, Paragraph 55), which is an emulsifier or binder, and thus deemed hydrophobic. Applicant disclosed that xanthan gum can be used as an emulsifier (see instant application, Page 9, lines 10-12). Oobae teaches that the addition of binders can improve the quality of the composition (Page 6, Paragraph 57).

18. Regarding Claims 2 and 3, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the non-saccharide ingredient to have been a hydrophobic substance such as an emulsifier, because Oobae teaches that the addition of such binders/emulsifiers can improve the quality of the composition. One of ordinary skill in the art would have been motivated to use an emulsifier or binder in order to ensure that the composition is of the highest quality possible, in order to be desirable to the consumer.

19. Regarding Claim 4, since Claim 2 does not require that the non-saccharide is hydrophilic, Oobae is deemed to meet the claim limitations as per the rejection of Claims 2 and 3 above. Furthermore, Mandai in view of Oobae teach the addition of coloring matters and flavoring materials to the powder composition (see Oobae, Page 6, Paragraph 52), which can be either hydrophilic or hydrophobic materials.

20. Regarding Claim 5, Mandai in view of Oobae teach that the non-reducing oligosaccharide produced by the invention is one where one or several glucosyl

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groups/residues, which can be seen as mono or di-glucosyl groups, are bound to both glucosyl groups/residues in trehalose (see Mandai, Column 2, lines 1-3). Such a non-reducing oligosaccharide is deemed a saccharide derivative of alpha, alpha trehalose because Mandai teaches that trehalose has glucoses bound to each other via the alpha-1 and alpha 1 linkages (see Mandai, Column 1, lines 23-24).

21. Regarding Claim 6, Mandai in view of Oobae teach that the saccharide derivative of alpha, alpha trehalose used in the invention is a saccharide that bears a trehalose structure at its end (see Mandai, Column 2, lines 64-67).

22. Regarding Claim 7, Mandai in view of Oobae teach that the oligosaccharide/non-reducing saccharide of alpha, alpha trehalose of the invention can be used in a powdered state and further mixed with other fills, vehicle and/ or binder (see Mandai, Column 5, lines 45-46) and such a powdered state is deemed an amorphous state. Reference is made to the 112 2<sup>nd</sup> rejection previously set forth, and since the term "amorphous" is open to interpretation, Mandai is deemed to meet the requirements of the claim because Applicant describes the powdery product as amorphous (See instant specification, Page 24, line 15).

23. Regarding Claim 8, Oobae teaches that the content of the trehalose excipient is dependent on the content of an active ingredient, the physical properties of a desired pharmaceutical composition, etc. but it is preferably about 1% to about 99.9 weight % in

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a solid pharmaceutical composition such as tablets (Page 5, Paragraph 48), which are deemed comparable to a powder composition because Oobae teaches that solid pharmaceutical compositions include tablets, granules, powder or the like (Page 5, Paragraph 45). Oobae further teaches that when the content of the trehalose excipient is less than 1 wt. %, desirable physical properties cannot be imparted to the pharmaceutical composition, and when the content of the trehalose excipient is more than 99.9 wt. %, the content of any active ingredient cannot be assured (Page 5, Paragraph 48). Oobae teaches that the excipient is preferably about 5 to about 80 wt %.

24. Therefore, in light of Oobae, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the amount of trehalose excipient added to the powder composition in order to ensure that the resulting powder composition has the desirable physical properties, while still maintaining the activity of any active ingredients that may be present. One of ordinary skill in the art would have been motivated to use a concentration between 5 and 80 wt% in order to ensure that the resulting powder composition is fully functional for its particular intended purpose.

25. Regarding Claim 9, Oobae teaches powders that were prepared, which contain trehalose, and where the components to be formulated into tablets are mixed, suspended or dissolved in a solvent and then subjected to spray drying, in order to improve the content uniformity (Page 2, Paragraph 8).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the powderization of the composition to be performed by spray drying, because Oobae teaches that spray drying formulations containing trehalose ensure improved content uniformity of the composition. One of ordinary skill in the art would have been motivated to use spray drying to ensure that the resulting composition was of uniform content, thereby creating a high quality end product.

27. Regarding Claim 11, Mandai in view of Oobae teach that the resulting powdered composition is a pharmaceutical composition (see Oobae, Page 3, Paragraph 18 and Page 5, Paragraph 45), and can also be used in food (Page 1, Paragraph 1).

28. Regarding Claim 12, Mandai in view of Oobae teach a powdery composition (see Oobae, Page 3, Paragraph 18 and Page 5, Paragraph 45), comprising a non-saccharide in the form of a xanthan gum (see Oobae, Page 6, Paragraph 55) and the saccharide derivative of alpha, alpha trehalose (see Oobae, Page 4, Paragraph 36 and rejection set forth in Claim 1).

29. Regarding Claim 13, Mandai in view of Oobae, are taken as cited above, teach a saccharide derivative of alpha, alpha trehalose (see Mandai, Column 1, lines 11-13 and Column 2, lines 1-3), and further teach a method of powderizing a non-saccharide ingredient, such as an emulsifier (see Oobae, Page 6, Paragraph 55), thus the

saccharide derivative of alpha, alpha trehalose is deemed a base for powderizing a non-saccharide ingredient.

30. Regarding Claim 14, Mandi in view of Oobae are taken as cited above, as for the rejection of Claim 1.

31. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandai et al. (U.S. Patent No. 5,780,620) in view of Oobae et al. (U.S.P.A. 2002/0042393) and in further view of Yoshiaki (JP Patent Application No. 08-020581).

32. Mandai in view of Oobae are relied upon as above for the rejection of Claim 1.

33. Mandai in view of Oobae are taken as cited above in the rejection of Claim 1.

Mandai in view of Oobae further teach that additives such as emulsifiers or binders can be used in the composition (see Oobae Page 6, Paragraph 55), as well as other functional substances such as lubricants (see Oobae, Page 6, Paragraph 56), which are deemed non-saccharide ingredients. Mandai in view of Oobae further teach that one or more active ingredients, the trehalose excipient, and optionally other additives are mixed and kneaded together with water, after which the mixture is compressed into tablets and dried (see Oobae, Page 6, Paragraph 61).

34. However, Mandai in view of Oobae do not specifically teach a step of powderizing an emulsion mixture containing emulsifier and water with a non-saccharide ingredient.

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35. Yoshiaki teaches a stable functional material excellent in storage stability and applicable to various kinds of food, drink and pharmaceutical applications without causing adverse effects on fragrance, tone, palatability, etc. (Page 2, Paragraph 4 and Page 3, Paragraph 14), wherein a mixture containing a functional substance (which is deemed a non-saccharide), alpha, alpha trehalose (Page 2, Paragraph 5), an emulsifier and water (Page 1, lines 15-23 of the machine translation of JP Application) are homogenized and then spray dried to obtain a powdered functional material (Page 1, lines 25-27 of machine translation of JP Application).

36. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the powdered composition as taught by Mandai in view of Oobae to have further comprised a step of powderizing an emulsion mixture and a non-saccharide, as taught by Yoshiaki, because Yoshiaki teaches that the resulting powdered functional material excels in storage stability and is applicable in foods, drinks and pharmaceutical applications, without causing adverse effects on the particular application chosen. One of ordinary skill in the art would have been motivated to combine an emulsion mixture with trehalose or a trehalose derivative, and a non-saccharide ingredient in order to create a stable, powdered composition that has a wide range of applicability, and does not impart any negative attributes on the particular application chosen.

***Conclusion***

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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February 20, 2009

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